UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: BAYER CORP. COMBINATION ASPIRIN PRODUCTS MARKETING AND SALES PRACTICES LITIGATION	:	**MEMORANDUM DECISION AND ORDER** 09 Md. 2023 (BMC) (JMA) ***ALL CASES***

Cogan, District Judge.

This case is before the Court on defendant Bayer Healthcare LLC's ("Bayer" or "defendant") motion to dismiss the Master Complaint ("Complaint"). The eleven above-captioned individual actions have been transferred to a multidistrict litigation docket established to consolidate, for purposes of coordinated pretrial proceedings, cases arising from claims that defendant misrepresented the virtues of Bayer Women's Low Dose Aspirin + Calcium ("Bayer Calcium"), which combines low-dose aspirin with calcium, and Bayer Aspirin with Heart Advantage ("Heart Advantage"), which combines low-dose aspirin with phytosterols.[1]

Plaintiffs allege that Bayer marketed the combination products as if they had been approved by the Food and Drug Administration ("FDA"); as if they were appropriate for long-term use; and as if Bayer Calcium were a source of calcium and Heart Advantage provided cardiovascular benefits. However, the combination products were not FDA-approved and, plaintiffs claim, were inappropriate for long-term use and incapable of delivering the health benefits touted on their packaging. Plaintiffs argue that someone could not take either

[1] Together, both products are referred to as the "combination products."

combination product as part of a daily low-dose aspirin regimen and get both the recommended daily dose of aspirin and the recommended daily dose of phytosterols or calcium. Someone taking Heart Advantage as part of low-dose aspirin regimen would get the recommended dose of aspirin, but only half the recommended amount of phytosterols. Similarly, someone taking Bayer Calcium as part of a low-dose aspirin regimen would get the recommended daily dose of aspirin, but only one-third of the recommended amount of calcium. Plaintiffs assert that Bayer's labeling was confusing because it commingled statements about the virtues of low-dose aspirin with those about the health benefits of calcium and phytosterols. In sum, rather than the whole being greater than the sum of its parts, the combination products, according to plaintiffs, were less.

Defendant presents several alternative grounds for dismissing plaintiffs' claims, the essence of which is that plaintiffs have alleged nothing more than a violation of the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.* (2009), which does not provide a private cause of action. In the alternative, defendant argues that plaintiffs' claims allege insufficient theories of injury and damages.

For the reasons set forth below, defendant's motion is denied.

BACKGROUND

Bayer is a major pharmaceutical company that has "been associated with aspirin" for over 100 years and describes itself as the "worldwide leader in the field of non-prescription drugs." One of its marquee products is low-dose aspirin. Bayer markets its aspirin products at the website www.wonderdrug.com and has long touted the benefits of a daily regimen of low-

dose aspirin. Aspirin is an analgesic, one of a class of drugs that act in various ways on the nervous system to decrease pain. Low-dose aspirin may be sold over-the-counter ("OTC") subject to an FDA monograph, which specifies what claims a manufacturer can make about the drug. 21 C.F.R. § 330.13 (2009). An aspirin manufacturer making approved claims does not need to go through the new drug approval ("NDA") process and can rely on the FDA monograph. In other words, any manufacturer can sell aspirin under the FDA monograph for aspirin as long as that manufacturer makes only claims permitted by the monograph.[2] All such a manufacturer need do is include standard directions and warnings, including that a long-term aspirin regimen should be pursued only under a doctor's supervision. Bayer sells its low-dose aspirin under the FDA monograph.

The FDA has approved unqualified health claims for calcium, for reducing the risk of osteoporosis, and phytosterols, for lowering cholesterol and reducing the risk of heart disease. Id. at §§ 101.72, 101.83. The FDA only permits unqualified health claims to be made after a "significant scientific agreement, among experts qualified by scientific training and experience . . . that the claim is supported by such evidence." Twelve nutrients have won this approval. Once awarded an unqualified health claim, the product's label is entitled to vaunt the nutrient's health benefits. 21 U.S.C. § 343(r) (2006). Calcium, the FDA found, reduces the risk of osteoporosis

---

[2] OTC aspirin labeling directed at consumers cannot include statements about its cardiovascular benefits because "[i]t is not possible . . . to provide adequate directions and warnings to enable the layperson to make a reasonable self assessment of these factors. Therefore, safe and effective use of aspirin to influence the risk of vascular events requires medical supervision by a practitioner licensed to prescribe drugs." Final FDA Rule for Professional Labeling of Aspirin, 63 Fed. Reg. 56,802, 56,808 (Oct. 23, 1998) (codified at 21 C.F.R. § 343.80). It is only the labeling for health care professionals that may include statements about aspirin's cardiovascular benefits. In 2000, the Federal Trade Commission ("FTC"), which enforces advertising requirements that parallel the FDA's labeling requirements, approved qualified health claims about low-dose aspirin's cardiovascular benefits. United States v. Bayer, Consent Decree, http://www.ftc.gov/os/2000/01/sterlingdecree.htm.

by contributing to peak bone mass. Accordingly, certain food and dietary supplements that provide at least 20 percent of the recommended daily amount of calcium may take advantage of the unqualified health claim and advertise the benefits of calcium. 21 C.F.R. § 101.72. Likewise, certain food and dietary supplements with the requisite levels of phytosterols can place "[a] health claim associating diets that include plant sterol/stanol esters with reduced risk of heart disease" on their labels. Id. at § 83.

Defendant has extolled Bayer Calcium and Heart Advantage as the sum of their respective parts. In addition to the qualified health claims about low-dose aspirin, Bayer Calcium employs the health benefit claim authorized for high-calcium foods and Heart Advantage employs the health benefit claim authorized for foods high in phytosterols. Each tablet of Bayer Calcium contains 81 mg of aspirin, the amount recommended for a daily aspirin regimen, and provides 300 mg of elemental calcium. It is labeled as a "PAIN RELIEVER/CALCIUM SUPPLEMENT" and for "ASPIRIN REGIMEN" use. The package labeling states that Bayer Calcium "Provides 300 mg of Calcium Which Helps Strengthen Bones To Help Fight Osteoporosis." There is a glass of milk next to the health benefit statements on the label and the product's name, which plaintiffs contend "represents that, like milk, Bayer Calcium is a source of dietary calcium." Although one tablet of Bayer Calcium is the recommended (and advertised) dose for someone on a low-dose aspirin regimen, that would provide only 300 mg of calcium, a fraction of the recommended daily dose.[3]

---

[3] In order to employ the health claims about calcium, the product must qualify as "high" in calcium, providing at least 20 percent of the recommended daily value. 21 C.F.R. § 101.72.

Bayer Calcium's label employs the health claims approved for calcium, including which groups are at an increased risk of developing osteoporosis (menopausal women and those with a family history of the disease) and that "[a]dequate calcium intake" is one factor that "may reduce the risk of osteoporosis." 21 C.F.R. § 101.72. The packaging also advertises Bayer Calcium as a source of aspirin and recites the health claims used on Bayer Low-Dose Aspirin: "Aspirin Protects Your Heart by Keeping Your Blood Flowing Freely." Additionally, identical to the packaging of Bayer Low-Dose Aspirin, the insert recites aspirin's cardiovascular benefits, including reducing the risk of stroke and heart attacks. According to plaintiffs, there is nothing to alert a consumer that the aspirin benefits recited in the insert were FDA-approved for use in low-dose aspirin, but not Bayer Calcium.[4]

On October 27, 2008, the FDA sent a letter warning that, because of Bayer Calcium's combined active ingredients and their combined labeled uses, it was a new drug that could not be sold OTC. Although each of Bayer Calcium's component parts could be sold OTC, the FDA's letter stated that the combination product would be subject to NDA because no other product with those ingredients and marketed for those uses had previously been commercially marketed. Current marketing, the FDA advised Bayer, misbranded the combination product because it lacked "directions under which the layman can use a drug safely for the purposes for which it is intended."

---

[4] "Regarding the use of Bayer Calcium as a source of aspirin, the package labeling states that the analgesic is intended to treat pain. However, other statements and representations on the package suggest that the product is also offered for long-term daily use in preventing or treating cardiovascular disease." Compl. at ¶ 40.

Bayer introduced Heart Advantage in early 2008. Each tablet contains 81 mg of aspirin, the standard daily dose, and 400 mg of phytosterols, half the recommended daily dose. Heart Advantage's packaging implies, plaintiffs contend falsely, that the combination product has all the virtues of its component parts.[5] The label advertises Heart Advantage as Bayer Aspirin "Plus Cholesterol Lowering Phytosterols," and describes the product as an "analgesic/phytosterol supplement." It distinguishes Heart Advantage as "[t]he only product that contains . . . aspirin, to protect your heart by keeping your blood flowing freely [and] Phytosterols, to help lower bad cholesterol." The label contains the FDA-approved health benefit claim that "[d]ietary supplements or food containing at least 400 mg of Phytosterols eaten twice a day with meals for a daily total intake of at least 800 mg, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease by lowering blood cholesterol." The FDA sent a warning letter identical to that for Bayer Calcium regarding Heart Advantage.

Each of the five named plaintiffs bought either Bayer Calcium or Heart Advantage after becoming concerned about their own health and seeing the combination product's promises -- decreased risk of osteoporosis or lowered cholesterol. Plaintiff Robert Nosbich's allegations, substantively identical to those of his co-plaintiffs, are illustrative.[6] Nosbich, an Illinois resident, saw Heart Advantage at his local pharmacy, read the claims about lowering cholesterol, and, in

---

[5] Plaintiffs allege that Bayer has long "promoted daily consumption of its Low-Dose Bayer Aspirin as a measure that consumers can take to prevent heart attacks" and charges it built on that marketing when it introduced Heart Advantage, advertising the new product "as intended for long-term daily use in preventing heart attacks and lowering cholesterol, and therefore in preventing and treating cardiovascular disease and hypercholesterolemia." Compl. ¶¶ 59–61.

[6] Each of the named plaintiffs claim that they purchased either Heart Advantage or Bayer Calcium in local drug stores for the same six-month period after seeing representations on the label about the product's health benefit.

reliance on those promised benefits, began taking Heart Advantage. From mid-2008 to early 2009, Nosbich purchased about one 30-pill-bottle per month. Nosbich's allegations of misrepresentations and harm are intertwined -- that Bayer misrepresented Heart Advantage's merits, its ability to actually decrease his cholesterol; and that Bayer misrepresented the fact that Heart Advantage was FDA-approved. But for these misrepresentations, Nosbich avows, he never would have purchased the product at all.[7] Had Nosbich known that taking a single tablet of Heart Advantage as his low-dose aspirin regimen would only provide half the recommended daily amount of phytosterols, which he argues is insufficient to lower cholesterol, then he would have purchased other low-dose aspirin available for a fraction of the price. A bottle of 60 tablets of Heart Advantage costs $10.99, approximately $0.18 per-pill,[8] whereas other low-dose aspirins cost as little as $4.99 for two bottles of 120 pills each, or just $0.02 per pill. Alternatively, if Nosbich had taken two tablets of Heart Advantage a day, as he would have in order to get the recommended daily dose of phytosterols, he would have ingested twice the recommended daily amount of aspirin, which can lead to health dangers of its own.[9] In sum, Nosbich alleges that it would have been impossible for him to get both the recommended daily amount of low-dose aspirin and phytosterols from Heart Advantage.

---

[7] As plaintiffs note in their Complaint, "Bayer included claims on [Heart Advantage's] packaging such as 'Plus Cholesterol Lowering Phytosterols' and 'Phytosterols, to help lower bad cholesterol,' that imply that the product may be used to treat, mitigate, or prevent hypercholesterolemia and coronary heart disease." Compl. ¶ 65. Such claims, however, require FDA approval and, plaintiffs allege, imply that if Heart Advantage were taken as part of a low-dose aspirin regimen, it would provide sufficient quantities of phytosterols to provide those benefits.

[8] A bottle of 60 tablets of Bayer Calcium costs $7.49, or $0.12 per pill.

[9] "[T]aking aspirin long-term should be under a doctor's supervision as the medicine is meant for short-term use. The long-term use of aspirin can cause serious side effects like gastrointestinal bleeding." Compl. ¶ 4

The named plaintiffs have brought this action on behalf of a putative nationwide class of consumers. They argue that while none suffered physical harm, all were injured in substantially the same sense -- they paid a premium for a product that they thought was superior to other low-dose aspirins because of defendant's false representations. Plaintiffs assert that had they known that the combination products were not FDA approved and, because of the inadequate amounts of calcium or phytosterols, could not provide the health benefits touted on their labels, they never would have purchased them at all. Accordingly, plaintiffs claim they are entitled to a full refund of the purchase price.

The named plaintiffs have brought suit under the consumer protection laws of their various states of residency (New York, New Jersey, California, and Illinois) and, in the alternative, similar statutes of some 43 other states. Plaintiffs also claim that defendant's misrepresentations violated express and implied warranties protected by state law. In addition to the nationwide class, whose claims plaintiffs argue will be governed by New Jersey law, plaintiffs have proposed a California subclass, on behalf of which they claim violations of the California Civil Code and Business and Professional Code.

STANDARD OF REVIEW

Bayer moves to dismiss for failure to state a claim upon which relief may be granted. The standard of review for a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) is well known and need only be restated briefly. The Federal Rules require that a complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." 8(a)(2). Plaintiff need only "give the defendant fair notice of what the . . . claim is and

the grounds upon which it rests." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 545, 127 S.Ct. 1955, 1959 (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47, 78 S.Ct. 99, 103 (1957)) (alteration in original). The Court accepts as true all well-pleaded allegations in the complaint and draws all reasonable inferences in favor of the non-moving party. See Conley, 355 U.S. at 45–46, 78 S.Ct. at 103; Desiano v. Warner-Lambert Co., 326 F.3d 339, 341 (2d Cir. 2003). Plaintiffs' complaint will survive so long as it states "enough facts to state a claim to relief that is plausible on its face," meaning that enough facts have been alleged that the court can reasonably infer that defendant is liable. Twombly, 550 U.S. at 570, 127 S.Ct. at 1974; 5B Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1356 (3d ed. 2009) [hereinafter "Wright & Miller"].

Complaints that sound in fraud, however, must meet a higher threshold than Rule 8's notice pleading. Pursuant to Rule 9(b), a plaintiff claiming fraud "must state with particularity the circumstances constituting fraud." The purpose of the heightened pleading standard is threefold: to provide defendant notice of the suit, protection from baseless charges, and sufficient information to frame a response. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). Rule 9(b) generally requires that a plaintiff specify the who, what, where, when and why of the alleged fraud; specifying which statements were fraudulent and why, who made the statements to whom, and when and where the statements were made. In re U.S. Foodservice Inc. Pricing Litig., Nos. 3:07 MD 1894, 3:06 CV 1657, 3:08 CV 4, 3:08 CV 5, 2009 WL 5064468, at *18 (D. Conn. Dec. 15, 2009) (quoting Mills v. Polar Molecular Corp., 12 F.3d 1170, 1175 (2d Cir.1993)). Courts have, however, taken a common-sense view and adopted the heightened pleading requirement to the facts of the case. Id. ("The Complaint does not make

allegations of the exact content, date, or sender of specific mail or wire transmissions alleged to be the predicate acts of mail or wire fraud. Nevertheless, the Court finds that the plaintiffs' allegations are sufficient in the context of this case because they have put the defendants on notice of the circumstances of the alleged fraud."). Thus, so long as the allegations are sufficiently particularized to put the defendant on notice as to what the plaintiff charges its fraudulent conduct consisted of, the date, time and place need not be pled with absolute precision. Id.; see Int'l Motor Sports Group, Inc. v. Gordon, 98 CIV 5611, 1999 WL 619633, *4 (S.D.N.Y. Aug.16, 1999) (explaining that Rule 9(b) "does not require that a complaint plead fraud with the detail of a desk calendar or a street map").

Plaintiffs pursuing fraud claims pursuant to state consumer protection laws may be held to Rule 9's heightened standard. See Ramirez v. STi Prepaid LLC, 644 F. Supp. 2d 496, 501–02 (D.N.J. 2009) [hereinafter "Ramirez I"] (applying Rule 9(b) to New Jersey consumer protection claims and Rule 8(a) to New York consumer protection act claims); Pelman v. McDonald's Corp., 396 F.3d 508, 511 (2d Cir. 2005) (holding that a private action under § 349 of New York's consumer protection act was only required to meet Rule 8's notice pleading standard because the law did not require proof of actual reliance and its protections "extend . . . well beyond common-law fraud to cover a broad range of deceptive practices).

DISCUSSION

Defendant argues that plaintiffs' allegations that the combination products were misleadingly labeled boils down to nothing more than charges that Bayer violated the FDCA by selling products that were not FDA approved, an impermissible private attempt to enforce the

FDCA. Because plaintiffs are claiming nothing more than a violation of the FDCA, defendant contends, their claims are preempted and fail to state a cognizable claim of fraud under the state law consumer protection statutes. In the alternative, defendant argues that plaintiffs have failed to allege an injury or a viable theory of damages.

I. Judicial Notice

As an initial matter, defendant has moved for judicial notice of several exhibits that may be divided in two categories: FDA documents and facts about aspirin. First, Bayer would have the Court take judicial notice of the publication and contents of three documents on the FDA website regarding the high standard for scientific agreement; the FDA's authority; and FDA enforcement options. Plaintiffs would limit judicial notice to the fact of publication alone. Second, Bayer moves for judicial notice of certain facts regarding aspirin -- that it has been sold in the United States for more than 100 years; is recognized as useful in preventing heart attacks and strokes by the American Heart Association; and that other low-dose aspirin is marketed for cardiovascular uses. Plaintiffs dispute these facts and argue that it would therefore be error to take judicial notice of them.

Although the purpose of a motion to dismiss is to test the legal sufficiency of a plaintiff's claims, taking all the allegations as true and reading them in the light most favorable to the plaintiff, the court is not required to reason in a vacuum. 5B Wright & Miller §1357, at 376. At any stage of the proceeding, the court may take judicial notice of facts "not subject to reasonable dispute" because such facts are "generally known" or "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned" without

converting a motion to dismiss into a motion for summary judgment. Fed. R. Evid. 201(b), (f). Courts routinely take judicial notice of extrinsic facts that may be independently, and reliably, verified. See, e.g., Hayden v. Paterson, 594 F.3d 150, 168 n.14 (2d Cir. 2010) (taking judicial notice of New York's 1967 Constitutional Convention); Garb v. Poland, 440 F.3d 579, 594 n.18 (2d Cir. 2006) (taking judicial notice of the workings of the Polish government and noting that "we have previously taken judicial notice of authoritative texts") (internal quotations and alterations omitted); Ganino v. Citizens Utils. Co., 228 F.3d 154, 167 n.8 (2d Cir. 2000) (noting that courts may take judicial notice of "well-publicized stock prices without converting the motion to dismiss into a motion for summary judgment" even when the stock prices were not annexed as an exhibit to the complaint or incorporated by reference).

Plaintiffs rely on Global Network Communications Inc. v. New York, 458 F.3d 150 (2d Cir. 2006), in which the Second Circuit vacated the district court's dismissal where it took judicial notice of the testimony of plaintiff's president in an unrelated criminal proceeding and defendant's final decision not to award plaintiff the contract as public records, and then relied on both as proof that plaintiff would be unable to make required payments. Notably, in Global Network Communications, the district court's decision rested on factual determinations it made based on the judicially noticed public documents. Id. at 157 ("Finally, we think the district court's improper factual finding regarding Global's ability to compensate the City," which was based on the testimony and the city's final determination, "pervades the court's decision and, therefore, vitiates its legal rulings on appellant's other claims."). That case is inapposite to the situation here, in which none of the facts defendant has submitted resolve a crucial factual issue. Rather, the FDA publications provide context and a means of measuring defendant's conduct.

Courts have taken judicial notice of regulations and their contents to measure the standard of defendant's behavior, which is analogous to the FDA publications, including an enforcement handbook, at issue here. See, e.g., Christman v. Skinner, 468 F.2d 723, 725–26 (2d Cir. 1972) (taking judicial notice of then-valid prison regulations). As to the facts about aspirin, plaintiffs' argument has no merit. One of the facts plaintiffs dispute is that aspirin has been sold in the United States for more than a hundred years. Yet in their Complaint, plaintiffs state that "[s]ince the late 1880s, Bayer has been associated with aspirin" and that Bayer's website advertises aspirin as "one of the most extensively studied drugs in history, with more than a 100-year track record of safety and efficacy."[10] Distinguishing between the statements is, for purposes of this motion, meaningless.

Pursuant to Rule 201(b), the Court takes judicial notice of the six exhibits. The facts set forth on the FDA website are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," widely recognized, and incorporated into federal regulations and leading cases. Similarly, the facts regarding aspirin and its marketing by other manufacturers are widely acknowledged and easily verified.

II. Preemption

Defendant attacks the adequacy of plaintiffs' complaints about the defects of Heart Advantage and Bayer Calcium, the gravamen of which is that plaintiffs have averred nothing

[10] Similarly, plaintiffs argue that the Court should not take judicial notice of the American Heart Association's recognition that aspirin has cardiovascular benefits or that other low-dose aspirins are marketed to consumers for cardiovascular uses. Yet the Complaint itself notes that one of the traditional reasons doctors prescribe aspirin is as a blood thinner for patients suffering from heart disease and that the FDA has approved statements about the cardiovascular benefits of aspirin. Compl. ¶¶. 3, 41.

more than a violation of the FDCA. As defendant argues in its brief: "Plaintiffs' claims fail, first, because they are [] private attempts to enforce the [FDCA] . . . Even if a state were to recognize it, a cause of action based on a failure to obtain FDA approval would be preempted as interfering with the FDA's approval process." Both arguments are built on the premise that plaintiffs' cardinal complaint is that Bayer sold unapproved drugs. Bayer's reading narrows plaintiffs' allegations to the fact that it sold Heart Advantage and Bayer Calcium without first winning FDA approval, which plaintiffs argue it was obliged to do because, although the components of each are FDA-approved, the combination products are new drugs that require FDA approval. "At the heart of the Complaint is the allegation, for each of the named plaintiffs, that he or she 'would not have purchased [Bayer's product] had [he or she] known that Bayer submitted [it] to the FDA." Bayer dismisses plaintiffs' allegations of the substantive defects in the products -- that it would be impossible to take either Heart Advantage or Bayer Calcium and get the recommended amount of low-dose aspirin and calcium or phytosterols -- as "irrelevant" without corresponding allegations of physical harm or deficient directions. Because plaintiffs have not claimed physical injury, defendant argues they have not been injured at all. Finally, defendant contends that plaintiffs' claims fail because they plead an insufficient "price inflation" or "price impact" theory of damages.

A. FDCA and preemption

Defendants rely heavily on the well-established principle that enforcement of the FDCA is the sole province of the FDA. 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); see Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S.Ct. 1012 (2001).

The FDCA's primary focus is ensuring that drugs are "safe, effective and not misbranded," which the FDA ensures by enforcing the regulations. Sandoz Pharm. Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 230 (2d Cir. 1990). In Buckman, the Supreme Court reaffirmed the long-standing principle that a private plaintiff cannot bring suit for a fraud upon the FDA. There, the plaintiff claimed that the manufacturer of medical screws made false representations to the FDA in order to win approval for the screws and that without these misrepresentations the FDA never would have approved the screws and plaintiff never would have been injured by them. The misrepresentation at issue in Buckman was not made to the plaintiff -- or consumers at large -- but to the FDA itself. The Supreme Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. at 348, 121 S.Ct. at 1017. The plaintiff's claims, which "exist[ed] solely by virtue of the FDCA disclosure requirement," failed because they were based not on traditional state law regulations of health and safety, but solely on the relationship between the federal agency and the regulated entity. Id. at 353, 1020.

Following Buckman, courts have distinguished preempted claims from viable ones in the following manner:

> The plaintiff must be suing for conduct that violates the FDCA . . . but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009); see Lefaivre v. KV Pharm. Co., No. 4:09CV00588, 2010 WL 59125, at *3 (E.D. Mo. Jan. 5, 2010). In other words, a state

law claim only endures if it manages to incorporate, but not depend entirely upon, an FDCA violation and is premised on conduct that would give rise to liability under traditional common law principles. On the other hand, if "defendant's conduct is not of this type," i.e., would not expose it to liability but for the FDCA, "then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under Buckman." Lefaivre, 2010 WL 59125, at *3 (dismissing implied warranty of merchantability claims because they were based not on "traditional state tort law that predated the FDCA regulations," but rather, "wholly dependent upon the federal violations and would not exist absent the federal violations"); see, e.g., Mylan Labs., Inc. v. Matkari, 7 F.3d 1130 (4th Cir. 1993) (barring plaintiffs from proceeding with false advertising claim premised on the theory that defendants had implied FDA approval "merely by placing their drugs on the market"); Braintree Labs., Inc. v. Nephro-Tech, Inc., No. 96-2459, 1997 U.S. Dist Lexis. 2372, at *22 (D. Kan. Feb. 26, 1997) (dismissing for failure to state a claim under the Lanham Act because the allegations turned on violations of FDA labeling requirements and holding that the "same general principals" governed common law unfair competition claims, which were also dismissed).

After Buckman, state law consumer protection statutes (and the Lanham Act) continue to serve their traditional complementary role with FDCA labeling requirements. Mut. Pharm. Co. v. Ivax Pharms., Inc, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (explaining that the primary purpose of the Lanham Act is protecting "commercial interests" from any unfair advantage gained by "false or misleading advertising," while the FDCA's primary purpose is "protecting the public by ensuring that drugs sold in the marketplace are safe, effective and not misbranded")

(internal quotations omitted); see Sandoz Pharm., 902 F.2d at 230. In order to avoid preemption, however, a plaintiff's claim must thread the needle described in Riley, showing that defendant has violated the FDCA, but that plaintiff's claims are not entirely premised on that violation and that defendant's wrongdoing would entitle the plaintiff to recovery under traditional state law principles. 625 F. Supp. 2d at 777.

Thus, in Wyeth v. Levine, 129 S.Ct. 1187 (2009), the Supreme Court reaffirmed that, despite a recent FDA preamble that the FDCA preempts all conflicting or contrary state law for drug labeling and safety, federal law remains only a floor upon which states can build additional protections. There, the plaintiff sued Wyeth for failing to adequately warn about the risk of administering an anti-nausea drug intravenously using an IV-push, whereby the drug is injected directly into a patient's vein, rather than the slower IV-drip, whereby the drug is introduced into a saline solution in a hanging intravenous bag and then enters through a catheter in a patient's vein. Wyeth argued that Levine's state law claims were preempted because the FDA had approved the drug and its labeling. In its analysis, the Court traced Congressional regulation of drug and drug labeling through the FDCA's 80-year history, explaining that Congress has consistently preserved the right of individuals to bring common law suits. Id. at 1196–99. "[Congressional] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. at 1200. Correspondingly, "the FDA has traditionally regarded state law as a complementary form of drug regulation" that provided "an additional, and important, layer of consumer protection that complements FDA regulation." Id. at 1202.

After Wyeth, federal drug labeling regulations continue to set only threshold requirements and states remain free to erect additional protections. See, e.g., Demahy v. Actavis, 593 F.3d 428 (5th Cir. 2010) (holding that FDCA did not preempt non-conflicting state law failure-to-warn claim based on alleged inadequacy of generic drug label); Bartlett v. Mut. Pharm. Co., Inc., 659 F. Supp. 2d 279 (D.N.H. 2009) (finding state law claims were not preempted where defendant could have strengthened warnings on generic drug without violating federal labeling regulations). The FDCA and the state law consumer protection statutes serve complementary, though somewhat overlapping, roles. "The FDCA . . . 'is not focused on the truth or falsity of advertising claims,' but is [] directed to protecting the public by ensuring that drugs sold in the marketplace are 'safe, effective and not misbranded,' a task vested in the FDA to implement and enforce." Mut. Pharm., 459 F. Supp. 2d at 933 (quoting Sandoz, 902 F.2d at 230). "The main purpose of the advertising restrictions set forth in the FDCA [] is not to protect consumers from deceptive advertising, but rather to further the FDCA's underlying goal of ensuring the safety of prescription drugs." In re Epogen & Aranesp Off-Label Mktg. and Sales Practice Litigs., MDL 08-1934, 2009 U.S. Dist. Lexis 58697, at *25 n.4 (C.D. Cal. June 17, 2009) [hereinafter "In re Epogen II"].

B. Misrepresentations

Guarding against false or deceptive advertising in the marketplace, including false claims of FDA approval, is within the province of false advertising suits and state law consumer protection claims, many of which were enacted to ensure an honest marketplace. See id. at *24–25 (explaining that in order to bring a state law consumer fraud claim, plaintiff needed to allege that defendant had made false or deceptive statements and dismissing plaintiffs' amended

complaint for failure to set forth specific instances where defendant made such statements). The very purpose of the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1.1 *et seq.* (2007) ("CFA"), was to "give consumers relief from fraudulent practices in the marketplace and to deter merchants from employing those practices." Furst v. Einstein Moomjy, Inc., 860 A.2d 435, 441 (N.J. 2004). Correspondingly, courts have found that it should be "construe[d] liberally to accomplish its broad purpose of safeguarding the public." Id.; see generally Cox v. Sears Roebuck & Co., 647 A.2d 454 (N.J. 1994). Even under the less expansive federal regulations, claims of misleading advertisements have long "encompassed [] more than literal falsehoods." Am. Home Prods. Corp. v. Johnson & Johnson, 577 F.2d 160, 165 (2d Cir. 1978) (internal citations omitted); see also Procter & Gamble Co. v. Chesebrough-Pond's, 747 F.2d 114, 118-19 (2d Cir. 1984) (explaining that false advertising claims "embrace[] innuendo, indirect intimations, and ambiguous suggestions' evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement"). "Were it otherwise, clever use of innuendo, indirect intimations, and ambiguous suggestions could shield the advertisement from scrutiny precisely when protection against such sophisticated deception is most needed." Am. Home Prods., 577 F.2d at 165. Although claims that turn on interpretation of an FDCA regulation are preempted, "some false statements made in connection with prescription drug marketing are actionable under state or federal law, even if their truth may be generally within the purview of the FDA." In re: Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1291 (C.D. Cal. 2008) (internal quotations omitted) [hereinafter "In re Epogen I"].

Thus, in Mylan Laboratories, the Fourth Circuit found that the plaintiff's claim could proceed where it alleged that the defendant had falsely represented that its product was

"bioequivalent" to the plaintiff's. Although FDCA regulations define bioequivalence, the court found that the plaintiff's claim was viable because it had alleged that the defendant's statement was literally false. 7 F.3d at 1138 (noting that in support of its claims, "Mylan has alleged that approval of the defendants' ANDAs had been obtained through fraud and ultimately was withdrawn and that the data for the ANDAs or bioequivalence studies had been falsified or was seriously unreliable") (internal quotations omitted); see also In re Bextra and Celebrex Mktg. Sales Practices and Prod. Liab. Litig., No. M: 05-1699, 2006 WL 2374742 (C.D. Cal. Aug. 16, 2006) (denying defendant's motion to dismiss allegations that Celebrex was falsely marketed as superior to competing drugs, which the FDA had already determined would be misleading) [hereinafter "In re Bextra"]; Grove Fresh Distrib., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 715 (N.D. Ill. 1989) (permitting plaintiff to rely on the FDCA definition of orange juice to support its claim that defendant misrepresented that its product was 100% orange juice from concentrate). Consistent with this line of cases, in In re Epogen I, the district court dismissed the plaintiffs' allegations that the defendant had illegally promoted off-label uses as misbranding claims, but found actionable allegations that the defendant issued a letter in which it falsely stated that patients were at increased risk of complications because of how the drug was being administered when the defendant knew that the actual cause of the increased risk of complications was contamination from syringe stoppers. Id. at 1291; see Healthpoint, Ltd. v. Allen Pharm., LLC, No. SA-07-CA-0526-XR, 2008 WL 728333, at *6 (W.D. Tex. March 18, 2008) ("Plaintiffs have alleged a specific false or misleading representation in Defendant's commercial advertising -- that Allan states and implies that AllanDerm is a generic equivalent to XenaDerm, when in fact it is not."). As the Healthpoint court noted:

> There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawfully marketed . . . and, on the other hand, a Lanham Act claim that a false statement has been made about a product. Even though the FDA has not required [defendant] to demonstrate the equivalence of [its drug to plaintiff's] . . . [defendant] is not free to make false or misleading statements about its product.

2008 WL 728333, at *10 (internal quotations omitted).

In Mylan Laboratories, the Fourth Circuit distinguished between the plaintiff's sufficient claim for false representations of bioequivalence from its inadequate claim that merely placing drugs on the market with standard inserts often used for FDA-approved drugs was sufficient to falsely imply that the drug was FDA-approved. The plaintiff's claims that the defendant falsely implied FDA approval failed for the same reason that its claims that the defendant falsely implied bioequivalence survived -- specificity. In order for the plaintiff's claims of misrepresentation as to the drug's FDA approval to survive, the court explained, it would have had "to point to *some* claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts." 7 F.3d at 1139; see, e.g., Healthpoint, 2008 WL 728333 (disallowing claims of implied FDA approval where plaintiff argued that use of the word "generic" implied FDA approval of drugs, neither of which was required to have FDA approval, to pharmacists). Whereas the plaintiffs had pointed to specific instances where defendant falsely implied bioequivalence, they failed to specify "any statement or representation in the defendants' advertising which declared proper FDA approval." Mylan Labs., 7 F.3d at 1139. Such a "fatal deficiency cannot be cured by contentions that the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow implies (falsely) that the drug had been properly approved by the FDA." Id. (internal quotations omitted)

False representations of FDA approval are evaluated consistently with claims of misrepresentations about other aspects of drugs -- where plaintiffs sufficiently detail their allegations and point to specific instances where defendants have made false or misleading representations, they have actionable claims. Thus, in Mutual Pharmaceutical Co. v. Ivax Pharmaceuticals, Inc., 459 F. Supp. 2d 925 (C.D. Cal. 2006), the district court held that plaintiffs presented viable claims that defendant had falsely implied that its drugs were FDA approved by placing them on comparative clinical databases. As Bayer does here, the Mutual Pharmaceutical defendants argued that plaintiffs were stating a non-actionable claim of marketing unapproved drugs. The court disagreed, explaining that: "It is not the simple act of defendants marketing a non-approved drug that Mutual seeks to combat, but the particular form that marketing has taken; a form that Mutual contends carries certain implicit false suggestions in the minds of the consumer that defendants' drug is FDA-approved." Id. at 939–40; see also Cottrell, Ltd. v. Biotrol Int'l, Inc., 191 F.3d 1248, 1253 (10th Cir. 1999) (finding that plaintiffs had stated a false advertising claim where they argued that defendant had advertised its cleaning product as if the EPA had approved it for certain uses, when the agency had not done so); Trafficschool.com, Inc. v. Edriver, Inc., 633 F. Supp. 2d 1063, 1072–73 (C.D. Cal. 2008) (noting that "many courts have found that false advertising claims can be based on actual or implied approval by an agency" and finding that plaintiffs had stated a false advertising claim for defendant's misrepresentation of itself "as an official government motor vehicles agency").

C. Application

Plaintiffs assert that Bayer made misrepresentations designed to lead consumers to believe that the Heart Advantage and Bayer Calcium had been FDA approved. First, plaintiffs

argue that Bayer's reputation gave the combination products the imprimatur of FDA approval, which was cemented by Bayer's repetition of the claims it makes on low-dose aspirin and use of FDA-approved health benefit claims as to phytosterols and calcium.[11] Plaintiffs contend that by employing valid FDA-approved statements about the virtues of the component parts of the combination products, Bayer falsely implied that the combination products were themselves FDA approved. Bayer does not dispute that it employed FDA-approved statements about phytosterols, calcium and low-dose aspirin in marketing the combination products, and argues that there was nothing wrong with doing so. According to Bayer, the FDA's approval of the claims about calcium, phytosterols and low-dose aspirin entitled it to use them on the combination products. It is immaterial, in Bayer's view, that the FDA never approved any claims as to the combination products themselves.[12]

Second, plaintiffs contend that defendant misrepresented the safety and efficiency of the combination products. Plaintiffs argue that Bayer misrepresented the efficiency of the combination products because it would be impossible to receive adequate amounts of calcium or phytosterols if taking them as part of a daily aspirin regimen. Although taking multiple doses

---

[11] Defendant devotes considerable effort to refuting an argument that plaintiffs don't make -- that selling products without FDA approval or marketing products for purposes which the FDA has not approved them is a violation of the FDCA, for which a private plaintiff cannot seek redress. See, e.g., In re Epogen II, 2009 U.S. Dist. Lexis 58697 (dismissing state law consumer protection claims where plaintiffs alleged only that defendant marketed drugs for off-label uses, not that the drugs were ineffective for such use); Anthony v. Country Life Mfg., 2002 U.S. Dist. Lexis 19445 (N.D. Ill. Oct. 9, 2002) aff'd 2003 U.S. App. Lexis 13622 (7th Cir. July 2, 2003) (finding that producing and marketing products that contained supplements not approved for use in food was not an unfair trade practice under state law where the ingredients were listed on the label and plaintiff did not claim any deception).

[12] Although the 2008 warning letters criticized Bayer's labeling, the FDA never pursued any enforcement action. Bayer argues that this amounts to tacit approval of its marketing and that plaintiff's claims are therefore preempted or merely allege a violation of the FDCA.

would provide the recommended amounts of calcium or phytosterols, it would be dangerous quantities of aspirin. As plaintiffs allege:

> To provide any putative benefit, the dosage of phytosterols necessary to be consumed equals 2 tablets of Bayer Heart Advantage. By contrast, a daily aspirin regimen consists of a single 81mg tablet. Thus, a person cannot simultaneously ingest the recommended dose of aspirin while obtaining any purported cholesterol lowering effects of phytosterol.

Compl. at ¶ 67. Likewise, plaintiffs claim that in order to provide any putative benefit, someone would have to take multiple tablets of Bayer Calcium, which would supply the recommended amount of calcium but multiples of the recommended daily dose of aspirin. Id. at ¶ 37. Because of this dosing conflict, plaintiffs argue that the combination products were neither as effective (at lowering cholesterol or providing calcium) nor as safe (because ingesting sufficient quantities of phytosterols or calcium would require double-doses of aspirin) as Bayer represented.

Plaintiffs have pointed to specific instances of how Bayer allegedly implied that the combination products were FDA approved, which brings the present case closer to Mutual Pharmaceuticals and Cottrell, in which the plaintiffs attacked not merely the marketing and sale of drugs in general, but the "peculiar form that marketing has taken as having a specialized, implicit meaning in the eyes of the consumer [] that the drug is FDA-approved." Mutual Pharm., 459 F. Supp. 2d at 941 (discussing Cottrell and distinguishing Mylan). In Mutual Pharmaceuticals, the court found sufficient allegations that, by placing its drug on price lists restricted to clinicians, the defendant misled pharmacists into believing that its drug had been FDA-approved. The court noted that the plaintiffs were not merely challenging the defendant's marketing of a non-approved drug, but the "particular form that marketing has taken," placing the drug on a "specialized and unique marketing channel used by drug manufacturers for FDA-

approved medications." Id. at 940. Analogously, in Cottrell, the plaintiffs charged the defendant, which manufactured cleaning products for use in medical facilities, with making four false representations on the product's label: (1) claiming the cleaner was effective for seven days, in violation of the Environmental Protection Agency's ("EPA") statutory clearance; (2) falsely implying that the EPA had approved the claims that the cleaner was effective for seven days; and (3) falsely claiming that the cleaner could be used for seven days after mixing. The Fourth Circuit found that the first claim was precluded as a private attempt to enforce the statute, but the second was viable because it was grounded in defendant's alleged deception of consumers, not statutory violations. As the Fourth Circuit explained, although the claims were "closely related," the first claim failed because it alleged that the label violated the statute, related regulations, and EPA enforcement actions, amounting to enforcement of the statute's "substantive provisions." 191 F.3d at 1254 n.6. The second claim, however, was viable because it "focuse[d] on Birex's representations directed at consumers, and assert[ed] that Birex's label claims put in commerce a false representation of EPA approval." Id.

Reading the Complaint in the light most favorable to plaintiffs, it alleges not a statutory violation, but that defendant made misrepresentations that the combination products had been FDA approved. Plaintiffs' first claim is viable because it focuses on representations directed to consumers and asserts that defendant put into commerce false representations of FDA approval. See id.; Trafficschool.com, 633 F. Supp. 2d at 1072–73. Moreover, in support of their argument, plaintiffs have pointed out specific examples of where they allege defendant made such misrepresentations.

Plaintiffs' second and third claims (that Bayer misrepresented the safety and effectiveness of the combination products) are both grounded in their dosing discrepancy argument. Plaintiffs allege that Bayer's labeling made the products appear to be all things to all people -- providing adequate sources of calcium or phytosterols as part of a low-dose aspirin regimen. This is a traditional claim of consumer misrepresentation, not an attempt to enforce the FDCA's labeling requirements. Jackson v. Balanced Health Prods., No. C 08-05584, 2009 U.S. Dist. LEXIS 48848, at *10–12 (N.D. Cal. June, 10, 2009) (rejecting defendants' argument that plaintiffs' claims that dietary supplement was misleadingly advertised were only attempts to enforce the FDCA "to the extent that Plaintiffs have alleged that Defendants made statements that were fraudulent"); In re Bextra, 2006 WL 2374742, at *11. According to plaintiffs, the combination products were advertised as appropriate for long-term use even though they were not; Bayer Calcium was advertised as a source of calcium even though it was not; and Heart Advantage was marketed as reducing cholesterol and providing cardiovascular benefits even though someone taking one tablet a day as part of a low-dose aspirin regimen would only ingest half the recommended amount of phytosterols. Although these statements touch on areas regulated by the FDA, and may even require reference to FDA definitions as to what the requirements are for adequate sources of calcium and phytosterols and what the dangers of larger doses of aspirin are, they are not preempted. See Jackson, 2009 U.S. Dist. LEXIS 48848; In re Epogen, 590 F. Supp. 2d at 1291. The misleading nature of the statement can be verified without relying on any special expertise of the FDA and is therefore properly before this Court. In re Epogen, 590 F. Supp. 2d at 1291-92. Although plaintiffs reference FDCA regulations and the 2008 warning letters, they do so for context and background information. In other words, plaintiffs have threaded the needle and alleged conduct that violates the FDCA but sounds in

traditional principles of state law and would give rise to recovery even had the FDCA never been enacted. Riley, 625 F. Supp. 2d at 777.

Defendant argues that the FDA's silence since the 2008 warning letters means that it has tacitly approved of the advertising, thereby preempting plaintiffs' state law false advertising claims. This is exactly the reasoning rejected in Wyeth. Even if defendant is correct and the labeling meets the floor established by federal regulations, there is nothing to indicate that it could not still be misleading and therefore actionable under state consumer protection laws. Moreover, in order to prevail on such a preemption argument, defendant would have to show not only that its labeling met federal requirements, but that it was impossible for it simultaneously comply with the state consumer protection laws. In short, even if the statements met the FDA's threshold requirements, they could still be misleading under state law consumer protection statutes. See In re Bextra, 2006 WL 2374742, at *11.

Finally, plaintiffs rely on FTC actions to show that the labeling claims were misleading. See, e.g., Am. Home Prods. Corp. v. Fed. Trade Comm'n, 695 F.2d 681, 697–98 (3d Cir. 1982) (holding that "[p]ervasive government regulation of drugs, and consumer expectations about such regulation, lend drug claims all the more power to mislead"). The question of whether consumers were misled is, of course, a factual one. At this preliminary stage, it suffices that plaintiffs have set forth facts that permit the inference that discovery will bear out their allegations. Twombly, 550 U.S. at 570, 127 S.Ct. at 1974; see Healthpoint, 2008 WL 728333, at *6.

For the reasons set forth above, the Court concludes that plaintiffs' claims are not preempted by the FDCA and allege that defendant misrepresented whether the FDA had approved the combination products, and the safety and effectiveness of the combination products.

III. Motion to dismiss under the laws of states other than those in which named plaintiffs reside

Bayer has moved to dismiss plaintiffs' claims brought under the laws of states other than those in which the named plaintiffs reside and where each made their purchases. The five named plaintiffs live, and purchased the combination products, in New York, New Jersey, Illinois, and California. Plaintiffs argue that New Jersey law will ultimately govern, but in the alternative, bring suit under some 43 state consumer protection acts.[13] Plaintiffs also invoke the express and implied warranty laws of 30 states.[14] Plaintiffs have broken out a California subclass.[15] Bayer argues that the causes of action plaintiffs bring in the alternative pursuant to the various state law consumer protection statutes and pursuant to the express and implied warranty laws of all states other than New York, New Jersey, Illinois, and California, should be dismissed because the named plaintiffs lack standing to bring suit in states other than their own and because the pleadings are inadequate.[16] Defendant's first argument confuses Article III standing with the

---

[13] Count II of the Complaint.

[14] Counts III and IV of the Complaint

[15] Counts VI, VII, VIII of the Complaint.

[16] Notably, the named plaintiffs have each specified where they saw the misleadingly packaged Heart Advantage or Bayer Calcium; where their purchases occurred; how long they continued purchasing the product; and how they were deceived. The Complaint also explains, in great detail, why the labeling was misleading.

adequacy of named plaintiffs in a class action and its second fails because plaintiffs' pleadings are sufficiently detailed.

A. Standing to bring suit under state laws in which named plaintiffs do not live

"The issue of standing is a constitutional one and should not be conflated with Rule 23 class action requirements." Ramirez v. Dollar Phone Corp., No. 09-CV-2290, 2009 WL 3171738, at *9 (E.D.N.Y. Oct. 1, 2009) (citing and quoting 1 William B. Rubenstein et al., Newberg on Class Actions § 2:7 (4th ed. 2008) for the proposition that individual standing is a distinct inquiry from the class prerequisites of Rule 23). Whether the named plaintiffs have standing to bring suit under each of the state laws alleged is "immaterial" because they are not bringing those claims on their own behalf, but are only seeking to represent other, similarly situated consumers in those states. Ramirez I, 644 F. Supp. 2d at 505 ("The Complaint makes clear that the so-called "sister state" consumer protection laws are only implicated by members of the putative class. Hence, the fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants' calling cards is immaterial."); In re NASDAQ Market-Makers Antitrust Litig., 169 F.R.D. 493, 504–05 (S.D.N.Y 1996) ("[T]he question of standing is totally separate and distinct from the question of plaintiff's right to represent a purported class under Rule 23."). As the district court explained in In re Grand Theft Auto Video Game Consumer Litig., No. 06-MD-1739, 2006 WL 3039993, at *3 (S.D.N.Y. Oct. 25, 2006), where defendants argued that the named plaintiffs lacked standing to bring claims under the laws of states other than those in which they resided:

> The relevant question . . . is not whether the Named Plaintiffs have standing to sue Defendants–they most certainly do–but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action. This question is . . . appropriately answered through the class certification process.

It follows that the sundry state law claims cannot be dismissed for lack of standing when there is no requirement that the named plaintiffs have standing to bring them. Under the guise of standing, defendant has raised the issues of adequacy of the representatives and whether there are common questions of law or fact that predominate over any questions affecting only individual members. Ramirez I, 644 F. Supp. 2d at 504–05 (relying on 7AA Wright & Miller § 1780.1). These are issues to be addressed at the class certification stage.

B. Standing to bring suit on their own behalf

At this preliminary stage of the litigation, the only relevant standing inquiry is that of the named plaintiffs. Defendant argues that because plaintiffs have not pled physical injury caused by defects in Heart Advantage or Bayer Calcium, they have failed to allege the cognizable harm required for Article III standing. W.R. Huff Asset Mgmt. Co. v. Deloitte & Touche, LLP, 549 F.3d 100, 106–07 (2d Cir. 2008) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992)). "In order to have standing, a plaintiff must first demonstrate with particularity that he has suffered a concrete injury-in-fact." Interfaith Cmty. Org. v. Honeywell Int'l, 399 F.3d 248, 254 (3d Cir. 2005). To determine injury-in-fact, a court will "consider [] whether the alleged injury falls within the 'zone of interests' that the statute or constitutional provision at issue was designed to protect." Anjelino v. New York Times Co., 200 F.3d 73, 88 (3d Cir. 1999). Economic injuries are sufficient for standing. Moreover, courts have long held that a plaintiff is injured, suffering an ascertainable loss, when he receives less than what he was promised. See

Ramirez I, 644 F. Supp. 2d at 501 (finding that the plaintiffs had alleged an ascertainable loss where they claimed that the calling cards they purchased did not adequately disclose per-minute charges and fees). Thus, plaintiffs' allegations that they were misled into purchasing a product that was less than what they bargained for are sufficient for Article III standing. Id.

C. Adequacy of pleadings of sundry state law consumer protection statutes

Defendant's second argument, that the claims under state laws other than those of New York, New Jersey, Illinois and California should be dismissed for failure to state a claim, also fails. Granting this motion would permit Bayer to accomplish indirectly what it cannot directly. As defendant acknowledges, it is widely acknowledged that choice of law is determined at class certification to determine whether there is commonality. Pirelli Armstrong Tire Corp. v. Walgreen Co., No. 09 C 2046, 2009 WL 2777995, at *3 (N.D. Ill. Aug. 31, 2009); Whitson v. Bumbo, 07-05597, 2008 WL 2080855, at *1 (N.D. Cal. May 14, 2008) (holding that defendant's argument that plaintiff had failed to state a claim because of variations between state laws was "raised prematurely" and would "be more timely and appropriately addressed . . . if and when plaintiff moves for class certification"); Labajo v. Best Buy Stores, L.P., 478 F. Supp. 2d 523 (S.D.N.Y. 2007); Rios v. State Farm Fire & Cas. Co., 469 F. Supp. 2d 727, 742 (S.D. Iowa 2007) ("[I]t would be more appropriate for the Court to address the commonality, i.e., conflicts of law analysis, during the class certification stage, after class discovery."). It follows that it would be premature to narrow the scope of state laws pursuant to which plaintiffs could pursue their claims at this early stage of the litigation.

On the other hand, plaintiffs cannot use class actions to escape pleading requirements. Although the connection between the named plaintiffs and the jurisdictions they invoke is not material, the adequacy of their pleadings is. Defendant argues that plaintiffs' pleading of the sundry state statutes is insufficient because they have merely listed them, failing to recite the requisite elements of a cause of action and the grounds for their entitlement to relief. "The pleader is required to 'set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist." Kost v. Kozakewicz, 1 F.3d 176, 183 (3d Cir.1993) (internal quotations omitted); see Twombly, 550 U.S. at 555, 127 S. Ct. at 1964–65 ("[A] plaintiff's obligation to provide the grounds for his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.") (internal quotations and alterations omitted). It follows that "[t]he mere listing of state consumer fraud statutes . . . is insufficient to state a claim." McGarvey v. Penske Auto. Group, Inc., 639 F. Supp. 2d 450, 465–66 (D.N.J. 2009) (citing McCalley v. Samsung Elecs. America, Inc., No. 07-12141, 2008 WL 878402, at *9 (D.N.J. Mar. 31, 2008)) (emphasizing that "[p]laintiff fails to allege even the elements of the various statutes, or facts permitting this Court to draw inferences that the elements exist").

Plaintiffs have outlined only the broad contours of the state law causes of action for states other than those in which they reside. That, however, is sufficient at this preliminary stage because, unlike the McGarvey plaintiffs, they have done more than "mere[ly] listing ... state consumer fraud statutes." 639 F. Supp. 2d at 465–66. Plaintiffs have drawn the connection between the statutes and defendant's offending conduct. This is sufficient for defendant and the Court to draw inferences that the elements exist. See id. at 464; Kost, 1 F.3d at 183. For

example, in Count II, where they plead in the alternative for violations of the consumer protection acts of some 43 states, plaintiffs allege that:

> The acts, practices, misrepresentations and omissions by Defendant described above, and Defendant's dissemination of deceptive and misleading advertising and marketing materials in connection therewith, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

Compl. ¶ 110.

This pleading is representative of those for the breach of express warranties claimed in Count III and the breach of implied warranties claimed in Count IV. In all, plaintiffs link defendant's actions to the elements of the state law causes of action and sketch the outlines of those causes of action. Cursory, yes, but especially when considered in conjunction with the detailed choice of law analysis to be conducted at class certification, the allegations are sufficient to survive defendant's motion to dismiss. See Rios, 469 F. Supp. 2d at 741–42.

Generally, consumer fraud cases are governed by the law of the state where the consumer resides. In re Grand Theft Auto Video Game, 251 F.R.D. at 146 (internal citations omitted) ("In analyzing putative, nationwide, consumer-protection class actions, several courts have determined that the law of the state where each plaintiff resides and purchased the relevant product should apply."). In their submissions, both sides focus their arguments on the CFA,

citing case law from California, New York, and Illinois. The Court will proceed accordingly, evaluating the sufficiency of plaintiff's pleadings pursuant to the CFA.[17]

A. CFA

"Any person who suffers any ascertainable loss of moneys or property, real or personal, as a result of the use or employment by another person of any method, act, or practice declared unlawful" may bring a CFA claim. N.J. Stat. Ann. § 56:8-19. "To state a cause of action under the CFA, a plaintiff must allege: (1) an unlawful practice by the defendants; (2) an ascertainable loss by plaintiff; and (3) a causal nexus between the first two elements -- defendants' allegedly unlawful behavior and the plaintiff's ascertainable loss." Parker v. Howmedica Osteonics Corp., 07-02400, 2008 U.S. Dist. Lexis 2570, at *5 (D.N.J. Jan. 14, 2008) (quoting New Jersey Citizen Action v. Schering-Plough Corp., 842 A.2d 174 (N.J. Super. Ct. App. Div. 2003)); see Ramirez I, 644 F. Supp. 2d at 500-01. First, the plaintiff must charge defendant with committing an unlawful act. "Unlawful practices" include "deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with

---

[17] It is worth noting that the state consumer protection statutes at issue are similar to, and modeled on, the FTC Act. Karlin v. IVF Am., 93 N.Y.2d 282, 290, 690 N.Y.S.2d 495, 712 N.E.2d 662 (1999) (discussing New York consumer protection laws). The Illinois Consumer Fraud Act prohibits "unfair methods of competition and unfair or deceptive acts or practices . . . in the conduct of any trade or commerce." 815 Ill. Comp. Stat. 505/2 (2009). In order to state a claim, a consumer-plaintiff must allege a deceptive act by defendant upon which it intended plaintiff to rely and which proximately caused plaintiff's injury. Similarly, New York provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce . . . are unlawful." N.Y. Gen. Bus. Law § 349(a) (McKinney's 2004). "Any person who has been injured by reason of any [such] violation" can bring a claim for false advertising. Id. at § 349(h). The state statutes, like their federal counterpart, are broad and intended to secure an "honest market place." Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, 85 N.Y.2d 20, 25, 623 N.Y.S.2d 529, 647 N.E.2d 741 (1995) (internal citation omitted). In fact, the New York consumer protection statutes are more broadly worded than those of New Jersey and plaintiffs pursuing such suits are only required to meet Rule 8(a)'s notice pleading requirements. Ramirez I, 644 F. Supp. 2d at 501-02.

the sale or advertisement of any merchandise." N.J. Stat. Ann. § 56:8-2. Second, the plaintiff must show that he suffered an ascertainable loss. "[A]scertainable loss has been broadly defined as embracing more than a monetary loss. An ascertainable loss occurs when a consumer receives less than what was promised." Ramirez I, 644 F. Supp. 2d at 501 (internal citations and alterations omitted). As the Second Circuit held in Desiano, applying New Jersey law, assertion of an economic injury and resulting damages are sufficient to meet the ascertainable loss requirement: "Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers, since they would not have bought Defendant's product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations." 326 F.3d at 349. Courts have found it sufficient where plaintiffs claim that but for defendant's misrepresentations they never would have purchased defendant's products. CFA plaintiffs have fallen short, however, where they alleged a price inflation theory, which New Jersey courts have found insufficient to show the requisite ascertainable loss or causation. See Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., 929 A.2d 1076 (N.J. 2007); New Jersey Citizen Action, 842 A.2d at 178 (rejecting use of the general fraud on the market or price inflation theory in a CFA suit as insufficient for showing the required causation).

Finally, although CFA claims sounding in fraud must meet the heightened pleading requirements of Rule 9(b), see, e.g., Ramirez I, 644 F. Supp. 2d 496, courts are cautioned to approach dismissal of such a claim "with hesitation." New Jersey Citizen Action, 842 A.2d at 177.

B. Application

Accepting the allegations set forth in the Complaint as true, and viewing them in the light most favorable to plaintiffs, they have stated a viable CFA claim. Plaintiffs easily meet the first requirement. As detailed at length above, plaintiffs have charged defendant with falsely implying that the FDA had approved the combination products and that they were safe and effective for their advertised uses.

Defendant contends, however, that plaintiffs founder on injury and causation. According to defendant, plaintiffs cannot show the requisite injury, because they were not physically injured by the combination products, and cannot show that defendant's misrepresentations caused any harm to them, because they alleged a price inflation theory of damages. First, defendant asserts that plaintiffs did not get less than they bargained for because the combination products provided what they promised -- low dose aspirin and phytosterols or calcium. This interpretation reads out plaintiffs' entire inadequate dosing argument, which is the foundational premise of its allegations that the combination products were substantively defective. Moreover, the fact that plaintiffs cannot point to any physical injuries is immaterial. As the Second Circuit explained in Desiano, the injury alleged is "unaffected" by whether anyone was physically injured. The Desiano plaintiffs were health insurers who alleged that the defendant's misrepresentations about the safety of its diabetes drug caused them economic loss as purchasers because, had they not been misled by defendant's misrepresentations, they never would have chosen to purchase its drug rather than cheaper available alternatives. 326 F.3d at 349. In Desiano, the Second Circuit rejected the same argument Bayer makes here -- that plaintiffs lack the ascertainable injury

required for a CFA claim without a showing that the drug was ineffective or they suffered from side effects.

As the Second Circuit explained in Desiano, if a drug company marketed a drug that was new in name only and more expensive than the old drug, purchasers would be able to claim they suffered an economic injury. Id. at 349–50. In the hypothetical, as in the case at bar, plaintiffs have not argued that defendant's misrepresentations caused the price of the product to rise, but that the misrepresentations were the very reason they purchased it at all.[18] Similarly, in In re Bextra and Celebrex Marketing, Sales Practices and Product Liability Litigation, MDL 05-01699, 2007 WL 2028408 (N.D. Cal. N.D. Cal. Jul. 10, 2007) [hereinafter "In re Bextra and Celebrex"], the district court found that plaintiffs had adequately alleged injury where they claimed that they purchased defendant's product because of advertisements that falsely presented it as superior to traditional drugs. But for defendant's misrepresentations, plaintiffs would have purchased the traditional drugs and received the same relief, at a fraction the price. Id. at *5-6.

---

[18] McLaughlin v. American Tobacco., 522 F.3d 215 (2d Cir. 2008), does not undermine Desiano's applicability here. In McLaughlin, the plaintiffs allegedly relied on the defendants' misrepresentations regarding the health effects of light cigarettes and were injured to the extent that they paid a premium for light cigarettes, which they would not have done had they known about the actual health benefits of light versus full-flavored cigarettes. The Second Circuit rejected the plaintiffs' claimed injury theory because it would permit expectation-based damages even though RICO, pursuant to which plaintiffs had brought suit, limits compensation for injury to business or property. Moreover, the court found that the misrepresentation would not have reduced the value of plaintiffs' cigarettes, but only induced them to buy lights rather than regulars. See In re Schering-Plough Corp. Intron/Temodor Consumer Class Action, No. 2:06-cv-5774, 2009 U.S. Dist. LEXIS 58900 (D.N.J. 2009) (discussing McLaughlin and distinguishing Desiano on the grounds that plaintiffs had failed to allege that they were mislead by the marketing, instead claiming only that defendant's misrepresentations induced physicians to prescribe defendant's drug for off-label uses). The key distinction is that even if defendants had been truthful, the McLaughlin plaintiffs still would have purchased cigarettes. The only difference would have been that they smoked regulars rather than lights.

In support of its argument that plaintiffs have made insufficient allegations of injury, defendant relies on cases where plaintiffs never contended that the product they purchased had a defect or harmed them. See, e.g., Riveria v. Wyeth, 283 F.3d 315, 319 (5th Cir. 2002) (finding that plaintiffs lacked standing where they did not claim physical injury or that the drug "was ineffective [] or has any future health consequences to users"); Whitson v. Bumbo, 2009 U.S. Dist. Lexis 32282, at *22–24 (N.D. Cal. Apr. 15, 2009) (finding that plaintiffs had failed to meet the injury requirement of California consumer fraud statutes where the "product serve[d] its purpose throughout its useful life"); Walus v. Pfizer, 812 F. Supp. 41, 44 (D.N.J. 1993) (refusing to permit recovery where product worked normally). These cases are inapposite. Here, in addition to the fact that plaintiffs thought they were buying an FDA-approved product, plaintiffs have explained in great detail how the combination products contained inadequate amounts of phytosterols or calcium to provide the health benefits defendant advertised and for which they paid a premium. Unlike the plaintiffs in the cases cited by defendant, plaintiffs have alleged a defect in the product and that it did not perform as promised.

Finally, defendant attacks plaintiffs' damages theory as alleging only that defendant's misrepresentations caused a general price increase. New Jersey courts have rejected such price-impact theories as inadequate to state the causation required by CFA. See, e.g., In re Schering-Plough, 2009 U.S. Dist. Lexis 58900, at *110–112.[19] "[F]raud on the market is essentially a

---

[19] Moreover, in In re Schering-Plough, upon which Bayer relies, the plaintiffs were bringing a civil RICO suit, which "incorporate[s] common law principles of proximate cause. Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA Inc., 344 F.3d 211, 219 (2d Cir. 2003) (internal citations and quotations omitted) . The Second Circuit has "cautioned against" broadly applying such a causation requirement to state law consumer protection statutes because states may require a lesser showing of causation and most have done so. Id. (quoting Desiano, 326 F.3d at 348).

creature of federal securities litigation," pursuant to which plaintiffs who purchased securities at a price inflated by defendant's misrepresentations are entitled to bring suit, and insufficient to show the causal nexus required by the CFA. Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., 929 A.2d 1076, 1088(N.J. 2007); see In re Schering-Plough, 2009 U.S. Dist. LEXIS 58900, at *110–11 (dismissing plaintiffs' CFA claims because they alleged only a price inflation theory of damages, which was insufficient to show that their injuries were proximately caused by defendant's conduct). Accordingly, courts have rejected price impact theories of damages in CFA suits. See, e.g., New Jersey Citizen Action, 842 A.2d 174 (holding that "fraud on the market" has no place in CFA suits because it would "fundamentally alter the concept of causation in the CFA context").

Plaintiffs deny asserting that defendant's misrepresentations caused the combination products to be more expensive than low-dose aspirin. Rather, they contend, those misrepresentations were the very reason they purchased the product at all.[20] In other words, as in Desiano, but for the misrepresentations, plaintiffs would have purchased a less expensive available alternative. 326 F.3d at 349; see generally In re Bextra and Celebrex, 2007 WL 2028408 (finding that plaintiffs had adequately alleged that defendant's misrepresentations that its product was superior to competing, lower-priced equivalents, were sufficient for an Illinois consumer protection suit because, but for the misrepresentations, plaintiffs would not have been prescribed defendant's drug). According to plaintiffs, defendant's misrepresentations were the very reason why they purchased the combination products. This is similar to the damages theory

[20] Should this argument fail, plaintiffs state that they will seek recovery under the "benefit of the bargain," or "out of pocket loss" methods of calculating damages.

the district court found adequate in In re Ford Motor Co. E-350 Van Prods. Liab. Litig., No. 03-4558, 2008 WL 4126264 (D.N.J. 2008). There, the plaintiffs alleged that Ford deceived them "into believing that they were purchasing a vehicle that could be used safely, legally and practically to accommodate and transport 15 passengers." The plaintiffs' purchase was premised on Ford's promise. They did not argue that they paid a premium for the vans, but that defendant's false promise induced them to purchase the vans. But for the promise, they never would have bought the vans at all. The district court distinguished this from "fraud on the market, because under that theory, a plaintiff must allege only that the price charged for the product at issue was higher than it should have been as a result of defendant's fraudulent marketing campaign." Id. (internal quotations omitted) Whereas a plaintiff pursuing a fraud on the market theory would have alleged that misrepresentations caused the price of all the products to increase, the Ford Motor court found that the plaintiffs were making a distinct damages argument:

> [H]ere, Plaintiffs allege that Ford's fraudulent acts and omissions caused Plaintiffs' damages in the form of diminution in value and loss of use. They do not claim that the price charged for the allegedly unsafe vehicles was inflated by a broad advertising campaign. Thus, unlike the plaintiffs in Merck and Schering-Plough, Plaintiffs here do not pursue the price inflation theory, nor otherwise allege circumstances associated with a change in price on the market.

Id. (internal quotations omitted).

Construing the complaint in the light most favorable to plaintiffs, and mindful of the "hesitation" urged by New Jersey courts when deciding motions to dismiss CFA claims, at this point in the litigation, it is simply too early to determine whether, as a matter of law, plaintiffs have pled only a legally insufficient fraud on the market theory of damages. Plaintiffs have

alleged enough for the Court to infer that they are arguing that defendant's false promises were the very reason they purchased the combination products and are, accordingly, seeking a full refund of the purchase price. Moreover, should this theory fail, plaintiffs have stated that they will seek to recover "the benefit of the bargain" or "out of pocket loss," both theories of damages that other courts have accepted in state consumer protection actions to put defrauded consumers in the position they would have been had they received that which they bargained for. See, e.g., Smith, Allen, Mendenhall, Emons & Selby, Inc. v. Thomson Corp., 862 N.E.2d 1006 (Ill. App. Ct. 2006) (noting that "benefit of the bargain," the difference between the product's value as sold and that it would have had if the representations were true, is sufficient for damages); Cayuga Harvester, Inc. v. Allis-Chalmers Corp., 95 A.D.2d 5, 465 N.Y.S.2d 606 (4th Dept. 1983) (applying the "out of pocket rule" and finding that plaintiff was entitled to the pecuniary loss he suffered because of defendant's deception).

C. Breach of warranty and unjust enrichment claims

Defendant argues that plaintiffs' breach of warranty and unjust enrichment claims fail for much the same reasons it argued that their state law consumer protection claims were preempted -- that plaintiffs' allegations boil down to an assertion that defendant was required to get FDA approval for the combination products. The gravamen of plaintiffs' breach of express and implied warranty claims, defendant contends, is that its failure to get FDA approval for the combination products rendered them defective. This ignores not only plaintiffs' allegations that defendant misrepresented the FDA approval of the combination products, but their detailed charges of substantive defects. Notably, in the cases defendant relies on, plaintiffs did not allege that the drugs were actually ineffective. See, e.g., Schering-Plough, 2009 U.S. Dist. Lexis

58900, at *6–7, *45–56 (noting that plaintiffs did not claim that the drugs did not work for their advertised purposes, only that they had not been FDA-approved and the health benefit claims were not supported by sufficient evidence).[21] As the Schering-Plough court itself highlighted, "there is a clear and decisive difference between allegations that actually contest the safety or effectiveness of the Subject Drugs and claims that merely recite violations of the FDCA, for which there is no private right of action." Id. at *47.

As explained in the preemption discussion above, plaintiffs have alleged far more than that defendant should have won FDA approval for the combination products before selling them to consumers. Plaintiffs claim that the combination products cannot fulfill the promises Bayer makes on their labeling and that Bayer falsely implied that the combination products had been FDA-approved. Moreover, plaintiffs point out specific instances where they claim that defendant made a promise, such as that Bayer Calcium's combination of aspirin and calcium helps "fight" osteoporosis, that plaintiffs claim the combination product could not fulfill. In sum, plaintiffs allege that Bayer is responsible for failing to live up to the terms of the promises that it made, the express warranty whose terms a seller defines for itself. See Jackson, 2009 U.S. Dist. Lexis 48848 (denying motion to dismiss where defendant held its product out as "all natural; and plaintiff claimed it was not).

Similarly, plaintiffs have made sufficient allegations that defendant breached an obligation imposed by law, as a result of which it retained profits from the sale of the

---

[21] Another reason Schering-Plough is of limited persuasive value here is that it dealt with civil RICO claims, not warranty claims.

combination products. Defendants argue that plaintiffs' unjust enrichment claims fail because plaintiffs alleged only that defendant violated the FDCA by selling unapproved drugs. This characterization does a gross disservice to the Complaint's allegations. As explained at length above, plaintiffs charge defendant with employing misleading statements about the virtues of the combination product to market them to consumers. Because of these misrepresentations, plaintiffs purchased the combination products and defendant retained those benefits. If the allegations in the Complaint are true, then defendant reaped a financial reward at plaintiffs' expense. This is sufficient to state a claim for unjust enrichment. See In re Chateaugay Corp., 10 F.3d 944, 957-58 (2d Cir. 1993).

CONCLUSION

For the reasons set forth above, defendant's motion to dismiss is denied.

SO ORDERED.

S/ BRIAN M. COGAN

U.S.D.J.

Dated: Brooklyn, New York
March 30, 2010